REMARKS

Claims 1, 8 and 14-29 were pending in the present application, and stand rejected in a final action mailed April 19, 2007. On October 19, 2007, Applicants filed a Notice of Appeal. The present amendment submission is being made in connection with a request for continued examination (RCE). Claims 1, 8 and 14-29 are canceled in the amendment above, without prejudice, and new claims 30-52 are added. Accordingly, claims 30-52 are pending. Applicants respectfully request reconsideration in view of the amendments above and the following remarks.

New Claims 30-52 Are Patentable

New claims 30-52 are added to define more particularly the subject matter sought to be patented. The addition of these new claims adds no new matter. Support for the newly added claims may be found in the specification as originally filed, for example as follows:

Support for claim 30 appears at least in Figures 1-3 and 10, and associated text.

Support for claim 31 appears at least in paragraphs 0016 and 0020.

Support for claim 32 appears at least in paragraph 0020.

Support for claim 33 appears at least in paragraphs 0019 and 0021.

Support for claim 34 appears at least in paragraph 0022.

Support for claim 35 appears at least in paragraph 0022.

Support for claim 36 appears at least in paragraph 0022.

Support for claim 37 appears at least in paragraph 0023.

Support for claim 38 appears at least in paragraph 0026.

Support for claim 39 appears at least in paragraph 0029.

Support for claim 40 appears at least in paragraphs 0020 and 0029.

Support for claim 41 appears at least in paragraph 0030.

Support for claim 42 appears at least in Figures 1-3 and 10, and associated text.

Support for claim 43 appears at least in paragraphs 0016 and 0020.

Support for claim 44 appears at least in paragraph 0020.

Support for claim 45 appears at least in paragraphs 0019 and 0021.

Support for claim 46 appears at least in paragraph 0022.

Support for claim 47 appears at least in paragraph 0022.

Support for claim 48 appears at least in paragraph 0022.

Support for claim 49 appears at least in paragraph 0023.

Support for claim 50 appears at least in paragraph 0029.

Support for claim 51 appears at least in paragraphs 0020 and 0029.

Support for claim 52 appears at least in paragraph 0030.

Applicants submit that newly introduced claims are patentable over the references of record, including the references upon which the rejections of the now canceled claims were based, namely U.S. Patent No. 6,937,899 to Sheldon et al. ("Sheldon"), and U.S. Patent No. 4,846,191 to Brockway et al. ("Brockway '191 patent"). The fact that Applicants distinguish Sheldon from the presently claimed subject matter should not be considered to be a concession that Sheldon is properly considered prior art under any sub-section of 35 U.S.C. 102.

In particular with respect to claim 30, Sheldon does not disclose or suggest a method that includes, among other things, "implanting within the subject a pressure sensing device comprising a pressure transmission catheter and a transducer in communication with the pressure transmission catheter, the pressure sensing device being implanted so that a distal sensing tip of the pressure transmission catheter is positioned within an artery but the transducer of the pressure sensing device remains outside of the artery;" "receiving, within the implanted cardiac defibrillator, cardiac electrical activity waveform information sensed by the electrodes and pressure waveform information for the artery sensed by the implanted pressure sensor;" and "providing the cardiac therapy in the form of electrical defibrillation stimulation if the processing circuitry of the implanted cardiac defibrillator determines that an evaluation of both the cardiac electrical activity waveform information and the pressure waveform information shows there is occurring an aberrant rhythm for which therapy is appropriate."

Sheldon, by contrast, discloses a method of detecting ischemia in which a pressure signal is "obtained by a pressure transducer deployed within the heart or vasculature," and discloses that alternatively "the pressure sensor could be positioned around a blood vessel." (Column 2, lines 43-46; see also column 4, lines 57-64.) In either case, the pressure sensors in Sheldon are

not, as recited in Applicants claim 30, "implanted so that a distal sensing tip of the pressure transmission catheter is positioned within an artery but the transducer of the pressure sensing device remains outside of the artery." Applicants use of such a pressure sensor in a therapeutic application and in the manner set forth in the present claims provides significant benefits that are not suggested or even contemplated by Sheldon or any other reference of record.

In particular, a significant population of patients who may obtain benefit from therapeutic devices such as implantable cardioverter-defibrillators (ICD's) choose not to have these devices implanted in them for fear of unnecessary and painful electrical stimulations (false positives). Thus, there is a need for a device that is able to make a better determination than what currently exists. Improvements in various detection algorithms that analyze only the cardiac electrical waveform are certainly useful, but do not entirely solve the problem.

As described in the background section of Applicants' specification, it is indeed known in the prior art that it is useful to use sensed hemodynamic information, or in other words sensed pressure waveform information, to determine, or confirm, whether a sensed electrical waveform is one for which a potentially painful electrical shock is necessary. The problem is not with using that information. The problem is how to do that in a manner that is safe and effective. This has proven to be a difficult problem. Past approaches of using endocardial pressure measurements (that is, from a chamber of the heart) made by leads extending through veins have the drawback of the lead occupying space in a vein that may already contain multiple other endocardial leads. Moreover, a lead placed in the heart may be subject to significant motion from the beating heart, which may pose challenges to obtaining a highly reliable pressure signal. Leads entering the heart are further subject to a high rate of failure.

In addition, the use of blood vessel cuffs, such as are disclosed in U.S. Patent No. 6,077,227 to Meisel et al. (referenced by Sheldon at column 4, line 63) to obtain a pressure signal from an artery for use in a therapy device, have also not been proven to be effective. The reason they have not proven to be effective is that signals from such sensors have been found to degrade over time, and thus are a non-optimal solution for a therapeutic device such as is claimed to obtain pressure information to help or confirm that an electrical cardiac waveform is a dangerous one for which a painful therapy should be provided. Further, similar arterial cuffs that

have been employed in animal studies to measure hemodynamic information have resulted in a significant rate of vessel erosion and subsequent rupture. In addition, it has proven necessary to keep a large array of sizes available, as fit to the artery is important to safety and accuracy.

Applicants' approach that is set forth in claim 30 provides a safe and effective means to obtain reliable pressure sensor information that can be used to determine, or confirm, that an electrical therapy should indeed be provided to the patient. It is also an approach that goes against conventional wisdom that it is not safe to leave a catheter in the artery of an ambulatory patient. However, Applicants' approach of providing only a small part of a pressure sensor – namely, the pressure transmission catheter – in a vein or artery (for example, in the subclavian artery), and using information from that sensor in a therapy device, is one that is neither disclosed nor suggested by the references of record. With Applicants' claimed subject matter, the smaller surface area of the sensor that is actually positioned within the artery makes the method safer, and there is less chance of thrombus developing. In addition, the pressure sensor is very light, and will therefore greatly reduce the risk of damaging the endothelial lining of the vessel, than other approaches that may be envisioned for measuring pressure using a sensor indwelling in the artery. Further, if the pressure transmission catheter were to accidentally pull out of the artery, given the small size of the portion of the sensor that extends into the artery (namely, the pressure transmission catheter), it is unlikely that any significant bleeding will result, a major safety concern with the use of other indwelling sensors used to monitor arterial pressure. As such, the approach set forth in Applicants' claim 30 provides significant advantages that are not disclosed or suggested by Sheldon.

In addition, the teachings Brockway '191 patent, even if considered along with the teachings of Sheldon, do not render the claimed subject matter obvious. The Brockway '191 patent does, of course, disclose a pressure transducer comprising a pressure transmission catheter and a transducer, wherein a distal portion of the catheter is positioned within a blood vessel but the transducer remains outside of the blood vessel. (See, e.g., Figure 1.) However, pressure sensors of a type disclosed in the Brockway '191 patent have been around for many years, and yet no one has recognized how they may be used advantageously and beneficially as described and claimed in the present application. Indeed, the Brockway '191 patent was filed in 1988, and

does not describe the sensor being used with an implantable therapeutic device or defibrillator. It is only described as being used in monitoring applications, and mainly in monitoring laboratory animals undergoing pharmaceutical drug testing. (See, e.g., column 1, lines 15-23; column 4, lines 18-38.) And while the Brockway '191 patent does describe that its disclosed pressure sensors may be used also in human applications (see column 10, lines 40-50), there is no disclosure or suggestion of using them in therapeutic applications.

Accordingly, Applicants submit that independent claim 30 and its dependent claims 31-41 are patentable over the references of record. Independent claim 42 is a system claim, and is patentable for at least the reasons discussed above in connection with claim 30, as are dependent claims 43-52.

Conclusion

Applicants submit that claims 30-52 are in condition for allowance, and requests that the Examiner issue a notice of allowance.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Examiner is authorized to charge Deposit Account No. 06-1050 $405 for the Request for Continued Examination fee and $1,115 for the extension fees. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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